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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,590	02/27/2004	Jiadong Zhou	NDTCO.018A	7770
20995	7590	11/18/2005	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			SCHLAPKOHL, WALTER	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/789,590

Applicant(s)

ZHOU ET AL.

Examiner

Walter Schlapkohl

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may

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 10-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/13/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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**DETAILED ACTION**

Receipt is acknowledged of the papers filed 10/31/2005. Claims 1-27 are pending. Claims 10-27 are withdrawn from consideration.

***Election/Restrictions***

Applicant's election of Group I in the reply filed on 10/31/2005 is acknowledged. Applicant's election of the following species is also acknowledged: U6 promoter for the siRNA expression cassette, a fluorescent dye as an indicator of cellular delivery and GFP as a sequence encoding a nuclear delivery indicator.

Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 10-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/31/2005.

***Information Disclosure Statement***

The information disclosure statement filed 2/27/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 5 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the limitation "in the same plasmid or vector" in lines 2-3 of the claim. There is insufficient antecedent basis for this limitation in the claim. Furthermore, because the sequence encoding the ds RNA and the sequence encoding the nuclear delivery indicator are comprised within the

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same siRNA expression cassette as required by claim 1, it is unclear how these components could be on separate plasmids or vectors. Which interpretation is required by claim 3: that the sequence encoding the ds RNA and the sequence encoding the nuclear delivery indicator are separable or that the siRNA expression cassette with the recited components are further limited by placement into a plasmid or vector?

Claim 5 recites the "siRNA expression cassette of claim 1 which expresses small RNA in mammalian cells." What are the metes and bounds of "small RNA?" Does "small RNA" refer to microRNA, small nuclear RNA, dsRNA, or mRNA of a particular length?

Claim 5 recites the "siRNA expression cassette of claim 1 which expresses small RNA in mammalian cells." Claim 5 is vague and indefinite because it is unclear how the siRNA expression cassette product is limited by "expresses small RNA in mammalian cells." Does this mean that there are different or specific structural elements required in the siRNA expression cassette which are required for expression in mammalian cells or is Applicant claiming an siRNA expression cassette in a mammalian host cell?

Claim 9 recites the limitation "wherein the promoter is tissue specific." There is insufficient antecedent basis for

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this limitation in the claim. Which promoter is being referred to: the promoter of the siRNA cassette of claim 1 or the promoter operably linked to the nuclear delivery indicator of claim 8?

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Lorens (WO 03/076592 A2; see entire document). Lorens teaches an siRNA expression vector with a promoter, a sequence encoding ds RNA between 24-29 bp and a sequence encoding a nuclear delivery indicator (see Example 1, pages 16-17). The nuclear delivery indicator could be any sequence on the vector that is transcribed and recognized with a probe (e.g., the ds RNA or the encoded GFP transcript).

Regarding claim 2, the indicator of cellular delivery is the Renilla GFP (page 16, line 33 to page 17, lines 1-2).

Regarding claim 3, the ds RNA and the Renilla GFP are on the same vector.

Regarding claim 4, the promoter used is a modified U6 promoter (page 16, line 32).

Regarding claim 5, the vector expresses small RNA.

Regarding claim 6, the GFP expressed by the vector is a fluorescent dye.

Regarding claim 8, the sequence encoding the nuclear delivery indicator is a sequence for GFP operably linked to a promoter (page 16, line 33 and page 17, line 1-2).

### **Citation**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Xu et al (Patent Application Publication 2004/0192629 A1, especially paragraph [0075]). Xu et al teach an siRNA further comprising an indicator of cellular delivery consisting of a dye useful for tracing the siRNA derivative in the cell.

### **Conclusion**

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant does submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.



Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter A. Schlapkohl whose telephone number is

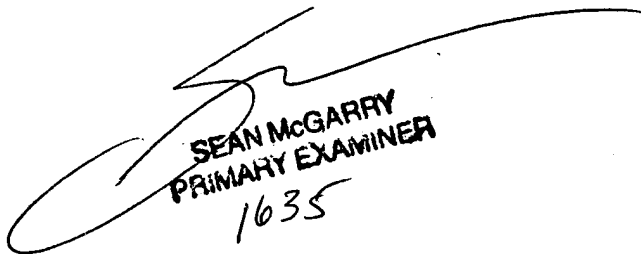
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(571) 272-4439. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office.)

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.  
Patent Examiner  
Art Unit 1636

November 14, 2005

  
SEAN MCGARRY  
PRIMARY EXAMINER  
1635